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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/727,582 | 12/05/2003 | Kenji Mori | MUR-037-USA-P | 7344 |
| 27955 | 7590 | 06/03/2005 | EXAMINER | |
| TOWNSEND & BANTA c/o PORTFOLIO IP PO BOX 52050 MINNEAPOLIS, MN 55402 | | | BOCKELMAN, MARK | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3762 | |

DATE MAILED: 06/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|-------------------|--------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/727,582 | MORI ET AL. |
| | Examiner | Art Unit |
| | Mark W. Bockelman | 3762 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 14 March 2005.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-9 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 5-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Hollinsworth USPN 569380 or Higo et al USPN 6,006,130.

Hollinsworth shows two electrode members (a), extraction pads (b) fixing members C, F' that are situated to intersect (cross each other) at pin f' in a rotatable manner with spring member H affixed thereto. Higo et al shows a similar arrangement with spring 37 and various electrode pad structures seen in figures 11(a) and 11(b). Applicant's statements of intended use provide no structural distinction since both references are capable of performing the functions recited.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3-4, 7-8 are rejected under by 35 U.S.C. 103(a) as being unpatentable over Tapper USPN 6,059,736 in view of Glikfeld et al. USPN 5,279,543. Tapper teaches and iontophoresis system that may extract analytes including glucose (as well as aspirin levels –see applicant's claim 4) using a sensor and an extraction period designed to complete extraction within ten minutes (see column 2 lines 22-28, as well as claim 7 of Tapper). A plurality of electrodes are provided in the system including drug delivery electrodes 16 a and b, return ground electrodes 63, 64 and sample analyzing electrodes 67, 68. An extraction pad 74 receives extracted body fluids for analysis. An ExacTech^R meter provides a readout for the level of glucose and time varying circuitry for controlling the sampling period (see claim 1 'means for varying time") are provided. With respect to claim 4, Tapper teaches that aspirin concentration can be measured, a substance capable of being delivered as well. Applicant differs from Tapper in reciting a voltage of less than 10 Volts. While Tapper teaches that his device may be used at higher voltages (i.e. above 15 Volts) to shorten sampling time it would have been obvious to alternatively use the more conventional lower voltages of 1-10 Volts for sampling as taught by Glikfeld et al (column 5 lines 65-70) if speed is not necessary.

Claims 2, 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tapper USPN 6,059,736 in view of Glikfeld et al USPN 5,279,543 and further in view of Cormier et al. USPN 6,219,574. Applicant differs in reciting that the extraction pad is an ion exchange resin and that the method (claim 9) includes sampling the mucosa membrane of a patient. Cormier et al teaches a sampling device that may be applied to

skin or mucosa (column 7 lines 40-47) for sampling. The pad used in sampling may be an ion exchange material to aid in retaining the analyte (column 3 lines 32-42). To have provided the Tapper device with a similar membrane and to have selected the mucosa as the sampling surface would have been obvious since such was well known at the time of applicant's invention as evidenced by Cormier et al..

Response to Arguments

Applicant's arguments filed 3-14-2005 have been fully considered but they are not persuasive. Applicant argues intend use for the Higo and Hollingsworth references. Both are capable of performing the recited function and thus meet any structural limitation that may be required by the stated intended use.

If applicant were to more precisely define how the fixing member arms form a cross with tensile spring to bias the electrodes in a grasping position the examiner would look favorably upon the claim. THe current claim language of "rotatably cross" seems to suggest other limitations than applicant's specification describes.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark W. Bockelman whose telephone number is (571) 272-4941. The examiner can normally be reached on Monday - Friday 8:00 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272 -4955. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MWB

May 30, 2005



MARK BOCKELMAN
PRIMARY EXAMINER